IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

APPLICANTS/APPELLANTS: WARREN SHAPIRO AND JON ANDERSON

APPLICATION NO.: 10/785,260

FILED: FEBRUARY 23, 2004

TITLE: COMPOSITIONS FOR PREVENTION OF CHEMICALLY INDUCED IRRITATION AND

DISCOLORATION

Examiner: Herbert J. Lilling

Group Art Unit: 1657 Confirmation No: 8880

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

On November 19, 2007, Applicants, now Appellants, Warren Shapiro and Jon Anderson, filed a timely Notice of Appeal from the Final Rejection of the Examiner dated August 17, 2007, in which claims 11-15, 19-26, and 28-32, which are all of the claims that are presently in issue in this case, were placed under Final Rejection.

This Brief is filed pursuant to 37 CFR Part 41, and particularly §41.37. The Brief Filing Fee of \$255.00 is submitted herewith, pursuant to 37 CFR §41.20. The term for filing this Brief is extended one month by this petition request and the filing of the one month extension fee of \$60.00 herewith.

An oral hearing is specifically not requested at this time.

I. REAL PARTY IN INTEREST

The application has been assigned by the Applicants/Appellants to Premier Specialties, Inc., by assignment recorded with the United States Patent and Trademark Office on June 6, 2007 at Reel/Frame 019390/0166. There are no other parties holding any interest herein.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals, interferences or judicial proceedings known to Appellants or Appellants' legal representatives which are related to, will directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 1-32 were originally pending in this case. Claims 1-10, 16-18, and 27 were previously cancelled. Claims 11-15, 19-26, and 28-32 are all of the claims currently pending and in issue in this case, and all of claims 11-15, 19-26, and 28-32 were examined and stand rejected. No claims stand allowed or confirmed. The rejections of the claims 11-15, 19-26, and 28-32 are hereby appealed.

IV. STATUS OF AMENDMENTS

All pending claims were finally rejected by the Examiner in a Final Rejection Office Action dated September 21, 2006 which was later rescinded as a Final Rejection and then by an additional Final Rejection Office Action of August 17, 2007. A response without claim amendments was filed on October 17, 2007 to address the issues in the August 17, 2007 Final Rejection. This Response was entered by the Advisory Action of October 31, 2007. Otherwise, no other amendments, cancellations nor addition of claims were made at any other time. Thus, the claims set forth in the Claims Appendix reflect the claims as they currently stand.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A concise description of the subject matter of each of the independent claims hereof follows with parenthetical references to the specification, by page, paragraph and line number. There are no drawings or reference characters to use for reference here. References to page, paragraph and line number are to the published version hereof; namely, US2004/0166132 A1...

The subject matter of an embodiment of the present application, as set forth in claim 11, for example, involves a composition (page 1, para. 0003, line 2, *inter alia*) for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga (page 1, para. 0003, lines 2-6, *inter alia*).

The subject matter of an embodiment of the present application, as set forth, for example, in claim 21, involves a composition (page 1, para. 0003, line 2, *inter alia*) for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of a root extract of Kaempferia Galanga (page 1, para. 0003, line 2, *inter alia*) dispersed in a carrier (page 1, para. 0003, lines 8-9, *inter alia*).

The subject matter of an embodiment of the present application, as set forth, for example, in claim 26, involves a composition (page 1, para. 0003, line 2, *inter alia*) for protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of ethyl p-methoxycinnamate (page 1, para. 0003, line 3, *inter alia*) dispersed in a carrier (page 1, para. 0003, lines 8-9, *inter alia*); wherein the ethyl p-methoxycinnamate is extracted from Kaempferia Galanga root (page 1, para. 0003, lines 4-5, *inter alia*).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 patentable under **35 U.S.C. 112,** first paragraph?

Are claims 11, 12, 13, 14, 15, 19, 20, 21, 22, 24, 25, 26, 28, 30, 31 and 32 patentable under **35 USC § 102(b)** over the U.S. Patent to Voss et al. (U.S. Patent No. 5,972,315; hereinafter "Voss")?

Are claims 11, 12, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 31 and 32 patentable under **35 USC § 102(b)** over the Japanese patent to Matsuda (JP40815734, hereinafter "Matsuda").

Are claims 11-13, 15, 19-21, 23, 25 and 31 patentable under 35 USC § 102(b) over the German patent to Schade (DE 19849514, hereinafter "Schade").

Are claims 13, 23, 28 and 29 patentable under 35 USC 103(a) as non-obvious over Voss?

Are claims 11-15, 19-26 and 28-32 patentable under 35 USC 103(a) as non-obvious over Matsuda?

VII. ARGUMENT

The argument herebelow is separated by the respective grounds of rejection to be reviewed herein, as well as by claim in various situations where claims are argued separately. Sub-headings are used only for convenience in presentation and readability to separate portions of the argument, but, are not intended to limit the substance of argument in any way. Separate arguments on a claim by claim basis are not separated by sub-headings, even where patentability is separately argued.

Claim Rejections - 35 U.S.C. §112 - Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31

All of the section 112 rejections are respectfully obviated and/or traversed here. These rejections will be addressed in the order in which they were made in the Final Rejection Office Action of August 17, 2007 ("Office Action" or "OA") and Advisory Action of October 31, 2007 ("Advisory Action").

Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected under 35 USC §112, first paragraph, in that the specification purportedly does not enable any person skilled in the art to make and practice the invention, and as purportedly failing to comply with the written description requirement. Specifically, the Examiner has stated that claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected because the specification allegedly does not enable one skilled in the art to which the claims pertain to make and practice the invention commensurate in scope with these claims. Furthermore, the Examiner stated that claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 stand rejected because the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention commensurate in scope with the claimed inventions; and furthermore, that "(t)he expression "root extract" does not define the ingredients. The Advisory Action reiterates the Examiner's position that the term "extract" renders the claims 11-15, 19-26, and 31 vague and indefinite in scope as to the structure(s) or compound(s) within the composition. Appellants respectfully traverse this rejection for at least the reasons discussed below.

The application adequately enables one skilled in the art to make and practice the invention. Appellants' extraction process is described in the "DESCRIPTION OF THE PREFERRED EMBODIMENT" section of the initial patent filing. Specifically, this description sets forth, page 1, paragraph 4, lines 2-8 of the publication version, US2004/0166132 A1, the steps of:

"placing the [Kaempferia Galanga] root in an alcohol path, heating in the alcohol bath to extract the cinnamate from the root; separating the alcohol solution from the root residue, and thereafter heating the alcohol extract for a time sufficient to evaporate substantially all of the alcohol therefrom."

The resulting "compound," i.e., root extract (as it is referred to throughout the specification) "is then used to prepare topical cosmetic preparations." Page 1, paragraph 4, lines 11-12. One skilled in the art can follow these very specific steps to obtain the end product of the extraction process.

The result of the extraction process is a definite product, which thus is clearly enabled by the very specific process set forth in the specification. Appellants have thus satisfied the enablement requirement of the first paragraph of section 112. Appellants' use of the term "root extract" throughout the specification is sufficiently definite, based on the definition of "root extract" clearly set forth in the specification, particularly as defined by the above-cited process for extraction which results in the definite root extract product. Practitioners possessing the present specification can "make and use" the root extract product hereof. This is all that is required for statutory "enablement".

In the instant Office Action, Final Rejection (August 17, 2007), the Examiner urges that "[t]he expression <u>"root extract"</u> does not define the ingredient(s)." Office Action, pg. 2, lines 13-14 (underlineation and bolding emphasis in the original). For enablement, this is not relevant, necessary, nor required. Practitioners need merely be taught how to "make and use" the invention. They have here, and thus the rejection is overcome, obviated or traversed.

In the Advisory Action (October 31, 2007), the Examiner reiterates his allegation that the Applicant has failed to provide the information for the claimed 'extracts'. Advisory Action, pg. 2, para. 2. Again, this is not relevant, necessary, nor required. Examiner asks for a decision by the Board of Appeals or other officials based on this specific issue. Advisory Action, page 2, paragraph 3. Simply put, the Examiner is refusing this application due to the invention's nature as an "extract". The "decision" requested by the Examiner is present in an abundance of existing, still valid case law regarding the specific issue of extracts and extraction. Particularly, the fact "that a new and useful product is the result of a process of extraction, concentration and purification does not defeat its patentability." Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 116 USPQ 484 (4th Cir. 1958) (emphasis added). Judge Learned Hand opined that

even if a composition of matter were "merely an <u>extracted</u> product without change, there is no rule that such products are not patentable." <u>Parke-Davis & Co. v. H.K. Mulford Co.</u>, C.C.S.D.N.Y., 189 F. 95, 103 (emphasis added). He continued on to say about that particular composition of matter that "while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. This was a good ground for a patent." <u>Id</u>.

More recently, an examiner rejecting a claim for indefiniteness under 36 U.S.C. 112 for not setting forth the entire composition chemically was reversed by the CCPA on that ground. In re Fisher, 57 CCPA 1099, 166 USPQ 18 (CCPA 1970). The examiner had stated the claim there "is indefinite for not setting forth the entire composition chemically . . . [and, that the claims] are indefinite in not setting forth with particularity the chemical structure or adequate physical characteristics to identify the composition." Id. at 1105. The CCPA found that "the board's affirmance of the indefiniteness rejection must be reversed." Id. Specifically, the court found that although the absence of limiting language, i.e. setting forth the entirety of the composition, may broaden a claim, such absence of limitation has a precise meaning. Id. at 1106.

Moreover, since a very specific and definite product is taught as being obtained by this very specific and definite disclosed process (see above), Appellants have also satisfied the written description requirement of section 112. See Merck & Co. v. Chase Chemical Co., 273 F. Supp. 68, 155 U.S.P.Q. 139 (D.N.J 1967) (finding that a patent fully complied with the requirements of section 112 when the specification described a crude active concentrate and tells how that concentrate can be prepared). Appellants did have possession of the claimed invention, as they had very definitely defined their root extract by the at least one definite extraction process set forth in the specification and above. Persons of skill in the art are also put on notice as to Appellants' possession of a definite product by the definition of the extract by the recitation of this extraction process. This is all that is necessary for the written description requirement of section 112.

In the instant rejection, the Examiner further urges that the "specification lack[s] support for the claimed <u>"root extract."</u> Office Action, page 2, lines 15-16 (underlineation and bolding emphasis in the original). Appellants have controverted this by showing that the specification indeed teaches how to obtain the "root extract" hereof. Similarly, as to the prior statement that "[t]he expression <u>"root extract"</u> does not define the ingredient(s)." Office Action, pg. 2, lines

13-14 (underlineation and bolding emphasis in the original); here also, this is neither relevant, necessary nor required to satisfy the statutory "written description." Appellants were in possession of a root extract and the method for achieving same and further recounted all this in the specification. Written description is thus also satisfied.

Furthermore, it is irrelevant, unnecessary and not required of Appellants to address the issues urged by the Examiner as to the "great number of compounds that exist[] in the extraction of this plant material" (Office Action, Final Rejection, page 3, Il 23-24); or the long listing in the Final Rejection, page 4, lines 3-15. These are simply not in issue for statutory enablement or written description.

Again, in this case, the structure of the initial application disclosure provides instructions for one skilled in the art to obtain a sufficiently definite "root extract" of Kaempferia Galanga. Despite the Examiner's listing of other elements that may be found in Kaempferia Galanga, the possible existence of such other ingredients is a mere peripheral curiosity to this case. As the specification sets forth, other compounds may be present in Kaempferia Galanga and may be found in the root extract; however, the scope and content of the root extract is defined by the extraction process and thus enabled and sufficiently described in the specification without need of more detail.

As a side note, the Final Rejection Office Action contains a note at the bottom of page 5, last two lines that the "Appellants has argued limitations on page 5 (presumably of their prior argument submittal, see Response of May 2, 2007) which limitations are not present in the instant claims pertaining to a product by process." First, as to enablement and written description, the claims are not directly the issue; rather, the specification is the issue, and, Appellants' present and prior response were so directed. Second, Appellants reference to the process for obtaining/defining the "root extract" of their case does not suggest nor require that the claims be product by process. That is another issue not properly addressed here; neither in rejection nor rebuttal.

As to the vague and indefinite rejection (presumably under 112, second paragraph), Office Action, Final Rejection, page 6, starting line 2, or line 5, the Examiner apparently imposes the requirement that an applicant must indicate in the claims the structure of the ingredients(s) or the compound(s) and the number of compound(s) effective for the claimed composition or a sufficient number of physical data to define the compound(s) or to submit a product-by-process

for claimed "root extract". Nevertheless, this is not the law, and, Appellants have complied with the statutory requirement. The structure of the root extract of the claims is given in the specification as set forth above, and is thus neither indefinite nor vague. Physical data for effectiveness of the overall composite structure are also represented (see Examples 4 and 5, pages 3 and 4 of the published specification, US2004/0166132 A1, paragraphs 29-44). The structure is definite and effectiveness data are presented. The number of internal compounds within the overall root extract which are effective for the claimed composition is of no matter; an extract as described hereby is effective regardless how many constituent elements may actually contribute to a particular result.

Converse to the examiner's assertion that the term "root extract" does not define the ingredients, or "does not define structures, physical or chemical properties of compounds,"

Office Action, page 6, lines 22-23, the extraction process defines the expression "root extract". The term is clear and it defines the "metes and bounds" of the claimed invention. Note,

Appellants have previously stated that use of the term "extract" is common in patent lexicography relating to derivatives of organic matter, as evidenced by the patents and prior art listed in the brief summary of the invention section of the initial patent filing. See also Exhibit

A, US Patent Office database of patents issued since 1976 with claims including the phrase "root extract"; resulting in at least 77 patents since 1976 (http://:patft.uspto.gov/...); which doesn't even begin to reach all "extract" claims for seed extracts, plant extracts, or extracts from other living or non-living matter. Use of the term "extract" does not render the claims of a patent indefinite nor vague, as often the term "extract" may be the most accurate and complete means of describing a constituent and essential ingredient of the claimed invention. This may be true here, where it may be incomplete to refer to the identity of the effective ingredients without making reference to the means of derivation from a root or other organic material.

Appellants submit that the terms "extract" and "root extract" and its further definition in the disclosure and in the claims are definite for at least the above reasons. Accordingly, Appellants respectfully request the reversal of the 112, first paragraph (presumably also or alternatively under 112, second paragraph) rejection of claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31, and respectfully request that these claims then be allowed.

Claim Rejections - 35 U.S.C. §102

All of the section 102 rejections are respectfully traversed here. These rejections will be addressed in the order in which they were made in the Final Rejection Office Action of August 17, 2007 as followed also by the Advisory Action of October 31, 2007.

Rejection of claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 by Voss

Claims 11, 12, 14, 15, 19, 20, 21, 22, 24, 25, 26, 28, 30, 31 and 32 stand rejected under 35 USC § 102(b) as purportedly being anticipated by Voss et al. (U.S. Patent No. 5,972,315; hereinafter "Voss"). Specifically, the Examiner has rejected these claims, "...in view of Example 1b, wherein the concentration of the ethyl p-methoxycinnamate is 2%." Appellants respectfully traverse this rejection for at least the reasons discussed below.

Appellants' specification and claims disclose and teach a skin-care product, or the root extract components thereof, for protecting against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation, as taught by Applicants' specification and claimed in independent claims 11, 21 and 26. Conversely, Voss describes its skin-care product throughout as "a new cosmetic skin-care product against ageing of the skin as an effect of light", as in col. 1, line 1; col. 1, line 55; and col. 2, line 27. By limiting the Voss cosmetic skin-care product to this one function, Voss specifically does not include, teach or suggest the element claimed and taught by Applicant, which is protection against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation.

Furthermore, the only mention of ethyl p-methoxycinnamate in Voss is in col. 4, line 47. The inclusion of ethyl p-methoxycinnamate, to the extent it is mentioned in this one instance, is as a UV B filter in the amount of 2.0 g in a total emulsion of 100 g. Voss limits inclusion of ethyl p-methoxycinnamate to this one Example 1b, and furthermore, limits the role of ethyl p-methoxycinnamate to the role of a UV B filter at a 2.0% concentration. By such limitation, Voss does not include, teach or suggest the "other than UV limitation" of Applicants' claims and rather, teaches away from use of ethyl p-methoxycinnamate as anything but a UV B filter in a 2.0% concentration.

Moreover, Appellants' composition of Kaempferia Galanga root extract is not taught or suggested by Voss whether for this or any other purpose, let alone that of Appellants' root extract serving an entirely different function than the Voss composition. Appellants' claimed composition is of a Kaempferia Galanga root extract as protective against the harmful effects of tyrosinase or chemically induced irritation but specifically does not include Kaempferia Galanga root extract as a protectant against UV radiation.

The Examiner appears to state that the products are identical or substantially identical, and to require that the Appellants to prove that the prior art products do not inherently possess the characteristics of the claimed product. In re Brown, 459 F.2d 531 (CCPA 1972). As a preliminary matter, the products are different. The claimed product here is specifically intended for "protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation". This is not an inherent characteristic of the Voss product, which "is based on UV-radiation-absorbing substances [necessarily] in combination with a free-radical scavenger system". Note, persons using the Voss product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Voss.

In order to sustain a rejection under 35 USC 102(b), the references cited, i.e. Voss, here, must teach or disclose each and every element of the claimed invention. Voss does not teach each and every element of Appellants' amended claims 11, 21 and 26. Thus, Appellants' claims 11, 21 and 26 are believed to be allowable over Voss. Appellants' dependent claims 12-15, 19, 20, 22-25 and 28-30 are also believed to be allowable over Voss because they depend from allowable independent claims 11, 21 and 26.

These section 102 rejections are thus obviated and/or traversed and may thus be overruled and/or reversed. Action to this end is respectfully requested.

Rejection of claims 11, 12, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 31 and 32 by

Matsuda

Claims 11, 12, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 31 and 32 stand rejected under 35 USC § 102(b) as purportedly being anticipated by JP40815734 (hereinafter "Matsuda") in view of paragraphs 26, 29, 31, 41-43 and 49 of that patent, which allegedly contain extracts of the claimed plant material within the scope of the claimed percentages. Appellants respectfully traverse this rejection for at least the reasons discussed below.

The Matsuda patent is entitled "UV Absorptive Skin Cosmetic", and is described as "a UV absorptive skin cosmetic characterized by having high safety and comprising a plant extract having UV absorptive effect". The objective of the invention in Matsuda is to protect the skin against harmful UV light, unlike the limitations of Appellants' patent claims. Matsuda is a UV protectant. Appellants' invention is a non-UV protectant. These are not identical and thus Matsuda does not anticipate. Note here also, persons using the Matsuda product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Matsuda.

In order to sustain a rejection under 35 USC 102(b), the references cited, i.e. Matsuda, here, must teach or disclose each and every element of the claimed invention. Matsuda does not teach each and every element of Appellants' amended claims 11, 21 and 26. Thus, Appellants' claims 11, 21 and 26 are believed to be allowable over Matsuda. Appellants' dependent claims 12-15, 19, 20, 22-25 and 28-30 are also believed to be allowable over Matsuda because they depend from allowable independent claims 11, 21 and 26.

These section 102 rejections are thus obviated and/or traversed and may thus be overruled and/or reversed. Action to this end is respectfully requested.

Rejection of claims 11-13, 15, 19-21, 23, 25 and 31 by Schade

Claims 11-13, 15, 19-21, 23, 25 and 31 stand rejected under 35 USC § 102(b) as purportedly being anticipated by Schade, DE 19849514 (hereinafter "Schade"), which allegedly teaches isoamyl p-methoxycinnamate which is allegedly within the scope of the claimed

inventions. Applicants respectfully traverse this rejection for at least the reasons discussed below.

The Schade patent, to the best of Appllants' understanding, references neither extract of Kaempferia Galanga nor a non-UV protectant. The reference cited by the examiner is isoamyl p-methoxycinnamate, also known as amiloxate. The mere fact that the Schade reference teaches a UV protectant for a potential substituent of a Kaempferia Galanga root extract does not teach or suggest the root extract itself nor that it would act as an "other than UV" protectant. Therefore, the Schade patent does not constitute disqualifying prior art.

In order to sustain a rejection under 35 USC 102(b), the references cited (i.e. Schade) must teach or disclose each and every element of the claimed invention. None of the cited references (including Schade) teaches each and every element of Appellants' amended claims 11, 21 and 26. Appellants' claims 11, 21 and 26 are believed to be allowable over Voss, Matsuda and Schade. Appellants' dependent claims 12-15, 19, 20, 22-25 and 28-30 are believed to be allowable over Voss, Matsuda and Schade because they depend from allowable independent claims 11, 21 and 26.

The section 102 rejections are thus obviated and/or traversed and may thus be overruled and/or reversed. Action to this end is respectfully requested.

Claim Rejections - 35 U.S.C. §103

All of the section 103 rejections are respectfully traversed here. These rejections will be addressed in the order in which they were made in the Final Rejection Office Action of August 17, 2007.

Rejection of claims 13, 23, 28 and 29 on Voss

Claims 13, 23, 28 and 29 stand rejected under 35 USC 103(a) as purportedly being obvious over Voss et al. (U.S. Patent No. 5,972,315; hereinafter "Voss"). Specifically, the

Examiner has rejected these claims, "...in view of Example 1b of Voss, wherein the concentration of the ethyl p-methoxycinnamate is 2% further in view of the disclosure which teaches that the percentage range is as low as 0.1%..." Appellants respectfully traverse this rejection.

Appellants incorporate their above arguments with regard to Voss, *supra*, and submit that Appellants' claims 13, 23, 28 and 29 are believed to be allowable at least, because: i) they contain limitations not taught or suggested by Voss; and ii) they depend from allowable independent claims 11, 21 and 26, respectively.

More specifically, Voss doesn't teach or suggest the limitations of the base claims 11, 21 or 26 including the "root extract" and "other than UV radiation" limitations, regardless the weight percents given. There is further no supplementation nor source or citation of a basis by the Examiner whether in or from Voss or some other prior art reference. Thus, the dependent claims 13, 23, 28 and 29 are not obvious from Voss and should be allowed.

Note, as a final matter, an Examiner taking "Official Notice" of the basic knowledge or common sense of a person of ordinary skill in the art to supplement the specific teachings of the art, must provide some form of evidence in the record to support such an assertion of common knowledge. In re Zurko, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d1693, 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection). Moreover, if the Examiner relies on his or her personal knowledge to supplement what is actually known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the supplementation. 37 CFR 1.104(d)(2).

Here, the Examiner provides no such evidence or affidavit supporting the Examiner's apparent taking of Official Notice and the assertion that Appellants' development would have been obvious to one skilled in the art. The Examiner has failed to provide any affidavit or other evidentiary support for the assertion that it would be obvious to extend the teachings of Voss for use in connection with a composition such as that disclosed in Appellants' application. In response hereto, Appellants respectfully request such evidence or affidavit according to rule 37 CFR 1.104(d)(2).

Rejection of claims 11-15, 19-26 and 28-32 on Matsuda

Claims 11-15, 19-26 and 28-32 stand rejected under 35 USC 103(a) as purportedly being obvious over Matsuda. Specifically, the Examiner has rejected these claims, "...in view of the broad disclosure as noted by the abstract as well as the examples noted . . . which extracts contain at least the ethyl p-methoxycinnamate in the extract." Appellants respectfully traverse this rejection for at least the reasons discussed below.

Applicants incorporate their above arguments with regard to Matsuda, *supra*, and submit that Appellants' claims 11-15, 19-26 and 28-32 are believed to be allowable at least, because: i) they contain limitations not taught or suggested by Matsuda; and ii) the dependent claims depend in relevant part from allowable independent claims 11, 21 and 26, respectively.

More specifically, Matsuda doesn't teach or suggest the limitations of the base claims 11, 21 or 26 including the "root extract" (apparently not an extract by the same or similar process of Appellants' description) or the "other than UV radiation" limitations. There is further no supplementation nor source or citation of a basis by the Examiner whether in or from Matsuda or some other prior art reference. Thus, both the independent and the dependent claims are not obvious from Matsuda and should be allowed.

Note, as a final matter, an Examiner taking "Official Notice" of the basic knowledge or common sense of a person of ordinary skill in the art to supplement the specific teachings of the art, must provide some form of evidence in the record to support such an assertion of common knowledge. In re Zurko, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d1693, 1697 (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection). Moreover, if the Examiner relies on his or her personal knowledge to supplement what is actually known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the supplementation. 37 CFR 1.104(d)(2).

Here, the Examiner provides no such evidence or affidavit supporting the Examiner's apparent taking of Official Notice and the assertion that Appellants' development would have been obvious to one skilled in the art. The Examiner has failed to provide any affidavit or other

evidentiary support for the assertion that it would be obvious to extend the teachings of Matsuda for use in connection with a composition such as that disclosed in Appellants' application. In response hereto, Appellants respectfully request such evidence or affidavit according to rule 37 CFR 1.104(d)(2).

CONCLUSION

The Appellants respectfully submit this appeal brief in response to the Final Rejection of the Examiner of August 17, 2007, and request reconsideration of the outstanding objections and/or rejections, reversal and/or overruling thereof, and consequent issuance of a notice of allowance for claims 11-15, 19-26, and 28-32 in this matter.

Respectfully Submitted,

Dated: February 19, 2008 By: _____

/peterbscull/

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CLAIMS APPENDIX

Claims 1 - 10 (previously canceled)

Claim 11 (previously presented): A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga.

Claim 12 (previously presented): A composition according to claim 11 containing from about 0.1 up to about 5.0 weight percent of the root extract of Kaempferia Galanga.

Claim 13 (previously presented): A composition according to claim 11 containing from about 0.2 up to about 1.0 weight percent of the root extract of Kaempferia Galanga.

Claim 14 (previously presented): A composition according to claim 11 in which said root extract of Kaempferia Galanga comprises ethyl p-methoxycinnamate.

Claims 15 (previously presented): A composition according to claim 11 for protecting mammalian skin from at least one of: harmful effects of tyrosinase, harmful effects of chemically induced irritation other than UV radiation, or discoloration.

Claims 16 -18 (previously canceled)

Claim 19 (previously presented): A composition according to claim 11 in which said root extract is dispersed in a carrier which is selected from the group consisting of nontoxic, nonirritating, or cosmetically acceptable.

Claim 20 (previously presented): A composition according to claim 11 in which said root extract is dispersed in a carrier which is selected from the group consisting of an emulsion, an anhydrous solvent, or a single phase system.

Claim 21 (previously amended): A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of a root extract of Kaempferia Galanga dispersed in a carrier.

Claim 22 (previously presented): A composition for protecting mammalian skin according to claim 21 in which said root extract of Kaempferia Galanga comprises ethyl pmethoxycinnamate.

Claim 23 (previously presented): A composition for protecting mammalian skin according to claim 21 containing from about 0.1% up to about 5.0% of the root extract of Kaempferia Galanga (wt/wt).

Claim 24 (previously presented): A composition for protecting mammalian skin according to claim 21 containing from about 0.2% up to about 1.0% of the root extract of Kaempferia Galanga (wt/wt).

Claim 25 (previously presented): A composition for protecting mammalian skin according to claim 21 in which said carrier is selected from the group consisting of an emulsion, an anhydrous solvent, or a single phase system.

Claim 26 (previously presented): A composition for protecting mammalian skin from discoloration or the harmful effects of tyrosinase or chemically induced irritation other than UV radiation comprising a preparation containing, in weight percent, an effective amount up to about 5 percent of ethyl p-methoxycinnamate dispersed in a carrier; wherein the ethyl p-methoxycinnamate is extracted from Kaempferia Galanga root.

Claim 27 (previously canceled)

Claim 28 (previously presented): A composition for protecting mammalian skin according to claim 26 containing from about 0.1% up to about 5.0% of ethyl p-methoxycinnamate (wt/wt).

Claim 29 (previously presented): A composition for protecting mammalian skin according to claim 26 containing from about 0.2% up to about 1.0% of ethyl p-methoxycinnamate (wt/wt).

Claim 30 (previously presented): A composition for protecting mammalian skin according to claim 26 in which said carrier is selected from the group consisting of an emulsion, an anhydrous solvent, or a single phase system.

Claim 31 (previously presented): A composition for protecting mammalian skin according to claim 21 in which said carrier is selected from the group consisting of nontoxic, nonirritating, or cosmetically acceptable.

Claim 32 (previously presented): A composition for protecting mammalian skin according to claim 26 in which said carrier is selected from the group consisting of nontoxic, nonirritating, or cosmetically acceptable.

EVIDENCE APPENDIX

EXHIBIT A:

US Patent Office database of patents issued since 1976 with claims including the phrase "root extract"; resulting in at least 77 patents since 1976 (http://:patft.uspto.gov/ ...)

Made of record by the Advisory Action of October 31, 2007 which entered the after final response of October 17, 2007 in which this material was first set forth.

RELATED PROCEEDINGS APPENDIX

No Related Proceedings information attached.

EXHIBIT A

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Results of Search in US Patent Collection db for:

ACLM/"root extract": 77 patents.

Hits 1 through 50 out of 77

Final 27 Hits

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Refine Search | actm/("root extract")

PAT.

NO. Title

- 1 7.282.224 T Pain relief composition
- 2 7.276.258 **T** Herbal extract and compound hipmoside and its analogues as anti-diabetic type II drugs from plant Pueraria tuberosa
- 3 7.250,180 T Anti-prostate cancer composition and therapeutic uses therefor
- 4 7.214.507 **T** Plant enzymes for bioconversion
- 5 7.201.930 T Licorice root extract oral patch for treating canker sores
- 6 7.175.987 **T** Compositions and methods for treatment of herpes
- 7 7.138.146 T Acrochordon alleviation
- 8 7,115,285 T Composition and method for appetite and craving suppression and mood enhancement
- 9 7.037.533 T Functional agent for decomposing nicotine and method of preparing the same
- 10 7,037.522 T Nocturnal muscle enhancing composition and method
- 11 7.025.955 **T** Method for maximizing scalp health and inducing enhanced visual and tactile hair quality
- 12 6.989.165 T Synergistic composition for treating hyperilipdemia
- 13 6.989.163 **T** Arrangement to enhance a woman's sexual sensitivity by a combination of phytoestrogens. L-arginine and menthol
- 14 <u>6.989.150</u> **T** <u>Cosmetic preparation of active substances with a synergistically increased radical protection factor</u>
- 15 6.953.593 T Sustained-release microencapsulated delivery system
- 16 6.888.043 **T** Feminine care products for the delivery of therapeutic substances
- 17 6.841.176 **T** Immunity enhancing supplements for lung support

http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtm... 10/16/2007

18 6,800,292 T Pomegranate fruit extract compositions for treating dermatological disorders

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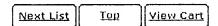
- 19 6.780.596 **T** Methods for determining the activity of complex mixtures 20 6.746.697 **T** Composition containing Heliopsis longipes root extract and oral carrier 21 6.719.966 **T** Creamy, stable homogeneous antiperspirant/deodorant composition 22 6.710.076 **T** Hydroxy-kojic acid skin peel 23 <u>6.676.974</u> T <u>Bioactive hexane fraction from Vetiveria zizanioides</u> 24 6.652.891 T Co-enzyme Q10 dietary supplement 25 6.630,130 T Sunless tanning cream 26 6.607.755 T Anti-aromatase pharmaceurical composition for controlling testosterone/estrone ratios 27 6.605,296 T Natural substances based agent 28 6.596.266 T Compositions containing minoxidil and saw palmetro for treating baldness 29 6.586.018 **T** Herbal composition 30 6.583,184 **T** Compositions having comfrey and methods for reducing retinoid-induced skin irritation 31 6.541,045 **T** Herbal composition and method for combating inflammation 32 6.541.042 **T** Therapeutically effective combination 33 6.537.592 **T** Extracts of kava-kava 34 6.524,626 T Ginseng berry topical products 35 6.524.624 T Two-part disinfecting systems and compositions and methods related thereto 36 6.521,268 T Antibacterial and anti-inflammatory compositions with Inula helenium L. extract and water soluble chitosan 37 6.447.814 **T** Chinese herbal composition for improving blood circulation and the method of preparing the same 38 6.440.402 **T** Photostable sunscreen compositions and methods of stabilizing 39 6,426,080 **T** Cosmetic preparation of active substances with high protection factor against free radicals
- 43 6.333,304 T Therapeutic compositions containing glucosamine, collagen and a bioflay anol for

40 <u>6.395,311</u> **T** <u>Multicomponent biological vehicle</u> 41 <u>6.352.685</u> **T** <u>External preparation for skin</u>

repair and maintenance of connective tissue
44 6.322.838 **T** Mint and/or fruit flavor compositions

42 6.348,503 T Method and topical treatment composition for herpesyirus hominis

- 45 6.319.523 T Composition and method for inhibiting oral bacteria
- 46 6.312.736 **T** Herbal composition to relieve pain
- 47 6,300,369 T Hydroxy-kojic acid skin peel
- 48 6.261.607 T Composition for promoting prostate health containing selenium and herbal extracts
- 49 6.242.012 T Herbal composition for promoting hormonal balance in women and methods of using same
- 50 6.241,987 T Dietary supplement containing saw palmetto, pumpkin seed, and nettle root



http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtm...-10/16/2007.

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ACLM/"root extract": 77 patents.

Hits 51 through 77 out of 77

Prev. 50 Hits

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Refine Search aclm/("root extract")

PAT.

NO. Title

- 51 6.221,372 T Cosmetic cleansing and skin care preparation containing plant and algae extracts
- 52 <u>6.197.343</u> **T** <u>Skin color improver</u>
- 53 6.187.313 **T** Composition and method for treating and preventing helicobactor-pylori-associated stomach gastritis, ulcers and cancer
- 54 6.156.355 T Breed-specific canine food formulations
- 55 6.080.410 T Method for reducing daily stress and anxiety in adults
- 56 6.071.962 T Oxa acids and related compounds for treating skin conditions
- 57 6.025.363 T Composition for suppressing appetite
- 58 5.977.120 T Composition for achieving an alert, yet calm state
- 59 5.958.334 T Combination capable of forming an odor barrier and methods of use
- 60 5.942.232 **T** Composition with plant additives and treatment method for reducing stress levels in fish
- 61 5.916.564 **T** Tripterygium wilfordii Hook F extracts and components thereof for immunosuppression
- 62 5,900,251 T Internal breath freshener and digestive aid
- 63 5.874.463 T Hydroxy-kojic acid skin peel
- 64 5.869.540 T Herbal treatments for improving skin appearance
- 65 5,773,014 T Compositions and methods for inhibiting the formation of unwanted skin pigmentation
- 66 5.770.207 **T** Dietary supplements containing kaya root extract, passion flower, chamomile flowers, hops, and schizandra fruit
- 67 5,660,833 T Anti-missive composition

http://patft.uspto.gov/netacgi/mph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtm... 10/16/2007

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- 68 <u>5.607.673</u> **T** <u>Purified extract of uvaria brevistipitata and a process for obtaining the purified extract therefor</u>
- 69 5.603,949 **T** Use of a tocopherol phosphate or one of its derivatives, for the preparation of cosmetic or pharmaceutical compositions and compositions so obtained
- 70 5.569.459 **T** Pharmaceutical compositions for the management of premensural syndrome and alleviation of menopausal disorders
- 71 5,510,113 T Composition based on hydrated lipidic lamelar phases or on hosomes containing at least one derivative of labdane, or a plant extract containing it; cosmetic or pharmaceutical, particularly dermatological composition containing it
- 72 5.455.033 T Medicinal composition for treatment of inflammation
- 73 5,424,331 **T** Pharmaceutical compositions and dietary soybean food products for the prevention of osteoporosis
- 74 <u>5.294.443</u> **T** <u>Tripterygium wilford II hook f extracts and components thereof for immunosuppression</u>
- 75 5.198.217 T Topical demulcent for viral and inflanunatory diseases of the skin
- 76 5.153.019 T Rice bran-honey based beverage product and process for making same
- 77 4,755,504 **T** Pharmaceutical composition from Tienchi

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